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CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20006

EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,153	HALL, JAN	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *30-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

REQUIREMENT FOR UNITY OF INVENTION

1. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 21-30, drawn to an implant in an assigned jawbone hole.

Group II, claim(s) 31-40, drawn to a method for building up a bone-based lateral support for an implant.

Newly submitted claims 31-40 are directed to an invention that lacks unity with the invention originally claimed for the following reasons:

Groups I-II lack unity of invention because even though the inventions of these groups require the technical feature of an implant comprising bioactive or osteoinductive material in or on the implant and arranged so that the implant is completely or partially covered by soft tissue or by a unit applied to the jaw bone so that the implant forms one or more spaces together with the soft tissue and/or the unit and the upper or lateral surface, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Wikesjö, et al. ("Augmentation of Alveolar Bone

and Dental Implant Osseointegration: Clinical Implications of Studies with rhBMP-2"; 2001; Journal of Bone and Joint Surgery; 83-A (Suppl. 1; Pt. 2): S136-45). Wikesjö teaches the use of recombinant human bone morphogenic protein-2 (rhBMP-2) for alveolar bone augmentation and dental implant fixation (background); the use of rhBMP-2 in a successful carrier system allows the BMP to act as a differentiation factor (i.e., a bioactive material; p. S1-138, right, 2nd paragraph); implants arranged in jaw bone holes are shown in Figure 1b, which are covered by the experimental treatments (containing the bioactive material), then the mucoperiosteal flaps are advanced and sutured to cover the teeth on implants for optimized healing conditions (an implant at least partially covered by soft tissue , where the treatment material forms a space together with the soft tissue covering the implant; Figure 1b); provision and maintenance of spaces by the experimental treatments is also taught at p. S1-139, last two paragraphs. Therefore, since the technical feature linking the inventions has been taught in the prior art, the technical feature is not "special"; accordingly the inventions are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-40 are withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows (a single specie is required for each of (i) and (ii)):

(i) A single disclosed growth-stimulating substance (GSS) specie or a single disclosed combination of GSS component species from (claim 1):

(i-a) matrix molecules;

(i-b) growth factors;

(i-c) differentiation factors;

(i-d) peptides with growth-stimulating properties; or

(i-e) a combination or two or more of (i)-(iv) (identify each component);

and

(ii) an arrangement of bioactive or osteoinductive material specie; from:

(ii-a) the implant is coated with an oxide layer having pores in which the bioactive or osteoinductive material is stored (claim 30);

(ii-b) a bioactive or osteoinductive material in or on the implant, but not including the arrangement of (ii-a) (claim 21); or

(ii-c) a non-implant unit is coated with bioactive or osteoinductive material on its surface exposed toward the implant (claim 28).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require

all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: all claims are generic for (i); claims 21-27, 29, 31-37 and 39 are generic for (ii).

5. The specie election requirement under (i) was required in the 11/16/2007 Office Action. The elected growth-stimulating substance specie, corresponding to specie (i-c), (i.e., differentiation factors), is also applicable to the invention of Group I, which has been constructively elected and are under examination.

6. Newly submitted claim 30 is directed to a specie that lacks unity with the species originally claimed for the following reasons:

The technical feature linking the species (under (ii)) is the presence of a bioactive or osteoinductive material in or on an implant. The species of an implant comprising bioactive or osteoinductive material in or on the implant (specie (ii-b)) has been taught in the prior art, as demonstrated in the rejection under 35 USC 102 (b), outlined below. Therefore, since the technical feature linking the species has been taught in the prior art, the technical feature is not considered "special". Accordingly, the species are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Since applicant has received an action on the merits for the originally presented species ((ii-b) and (ii-c)), these species have been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 30 is withdrawn from consideration as being directed to a nonelected specie. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

7. Applicants' arguments, filed 8/5/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

8. Applicant's arguments with respect to the rejection(s) of claim(s) 1-20 under 35 USC 101 and under 35 USC 112, 2nd paragraph have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

The rejections are withdrawn due to the claim amendment canceling these claims.

9. Applicant's arguments, see pp. 9-10, filed 8/5/2008, with respect to the written description rejection under 35 USC 112, 1st paragraph have been fully considered and are persuasive. The rejection of claims 1-20 has been withdrawn.

10. The rejection of claims under 35 USC 102 and 103 are moot, due to the canceled claims. However, the following rejections, applicable to the new claims, are necessitated by amendment.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 22, 26, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. This rejection is necessitated by the claim amendment adding all new claims.

14. Claim 29 recites the limitation "the apparatus" in the first line. There is insufficient antecedent basis for this limitation in the claim. There is no reference to an apparatus in the independent claim 21. Since there are several different materials recited in the claim, including a jawbone, it is not clear which of these is referred to by this term.

15. Claim 22 recites the "real" centerline of the jaw bone in the horizontal plane. It is not clear whether this is the same as the observed centerline or an extrapolation of the jaw line for tooth holes with defects, such as atrophied bone; i.e., it is not clear whether this correspond to the dashed line (4) of Figure 1 or a moving line that is half way between the inner line (between 2 and 3) and line 5 (not drawn in the Figure).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 21-22 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wikesjö, et al. ("Augmentation of Alveolar Bone and Dental Implant

Osseointegration: Clinical Implications of Studies with rhBMP-2"; 2001; Journal of Bone and Joint Surgery; 83-A (Suppl. 1; Pt. 2): S136-45).

This rejection, previously made for canceled claims, is extended to the new claims, necessitated by the claim amendment.

As pointed out previously, Wikesjö teaches use of recombinant human bone morphogenic protein-2 (rhBMP-2) for alveolar bone augmentation and dental implant fixation (background); the use of rhBMP-2 in a successful carrier system allows the BMP to act as a differentiation factor (a bioactive material that is a differentiation factor; p. S1-138, right, 2nd paragraph); implants arranged in jaw bone holes are shown in Figure 1b, the model of the figure is named the "critical-size supraalveolar peri-implant defect model", and is useful for the study of dental implant osseointegration (p. S1-138, 1st paragraph); the biomaterials used were mixed with autologous blood (a cell containing body fluid), then defects received various combinations that included rhBMP-2 (paragraph spanning pp. S1-138-9); implants placed in defects that received rhBMP-2 exhibited increased bone formation along the exposed implant surface compared to controls (a bioactive material on the implant; p. S1-140, right, 1st paragraph); clinically significant vertical and horizontal gain of alveolar bone was observed upon application of rhBMP-2/decalcified bone matrix (DBM)/ blood onlay, followed by implant placement into the newly formed ridge (Figure 4; p. S1-141, right, 2nd paragraph). These arrangements involve an implant covered (at least partially) by soft tissue, wherein the implant forms spaces into which body fluid penetrates and bioactive/ osteoinductive material comprising matrix molecules (DMB, for example), growth factors (rhBMP-2 acts

as a growth factor, see p. S1-141, 2nd paragraph) and a differentiation factor (rhBMP-2). This description includes all required limitations of claim 21.

Figure 7b and c shows implants in a position that is offset in relation to the centerline of the jaw, as required in instant claim 22, outer thread parts have greater degree of exposure on one side than the other, three and two implants arranged in the jaw bone are show in Figure 1b and 6a and 6b, two different irregular depths are apparent in Figure 6a, Figure 6b shows bone base lateral support has substantially filled the defects, both implants appear to have nearly the same degree of recessing after the stage of incorporation (figure 6b); placement of rhBMP-2 material adjacent to the implant would result in a greater degree of exposure to the space(s) formed when rhBMP-2 material is placed adjacent to the implant.

With respect to claims 24-25, the placement of rhBMP-2 around the implants would be a "unit" covering the exposed surface of the implant, such molding would take the shape of the implants giving an internally curved surface directed toward the exposed surface of the implant (Figure 1b, legend). With respect to claims 26-27, the implant shown in Figure 4 c has an exposed surface that looks to be nearly 180° (the view is "circumferential", but the same exposure would also be apparent if the photograph had been taken from the height direction). With respect to claim 28, the rhBMP-2 formed around the implant as described in the legend of Figure 1 b would have rhBMP-2 "coated on its surface exposed toward the implant". With respect to claim 29 the implants shown in Figure 1 b have a threaded outer surface.

Applicant argues the rejection is improper because the reference does not describe every element set forth in the claims; specifically, the terms "in or on the implant" and the formation of "spaces together with the soft tissue and/or a unit and the upper or lateral surface(s) of the jaw bone" are alleged not to be taught. This argument is not persuasive. As referenced in Figure 1b, Wikesjö teaches experimental treatments (contain the elected differentiation factors, rhBMP-2) are placed/molded around the teeth; the mucoperiosteal flaps are then advanced and sutured to cover the teeth on implants for optimized healing conditions. The carriers (containing the differentiation factors), so used provide and maintain spaces (as described, for example, on p. S1-139, last two paragraphs). The placement and/or molding of experimental treatments around the teeth results in a bioactive material "on the implant"; the spaces between implant and soft tissue would be formed and filled by the bioactive material, in the covering of the implants of Figure 1b by the flaps, as taught in the reference.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the rhBMP-2 is not part of the implant, per se) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims only require a bioactive or osteoinductive material in or on the implant (and said implant is in a jawbone hole), not that such material is part of the implant; the required relationship is taught by Wikesjö.

Claim Rejections - 35 USC § 103

18. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

19. Claims 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wikesjö, et al. ("Augmentation of Alveolar Bone and Dental Implant Osseointegration: Clinical Implications of Studies with rhBMP-2"; 2001; Journal of Bone and Joint Surgery; 83-A (Suppl. 1; Pt. 2): S136-45) as applied to claims 21-22 and 24-29 above, and further in view of Pirhonen, et al. (US 2003/0105530 A1; 2003 Jun 5; filing date 2001 Dec).

This rejection, previously applied to the canceled claims, is extended to the new claims, necessitated by the claim amendment.

Wikesjö does not teach a different concentration of GSS on the portions of the exposure than the other portions, required by claim 23. Pirhonen teaches implants over bone defects in the bony tissue surrounding a dental alveolus (units; Figures 2a & 2b; paragraphs 0021-0022) and a periodontal defect and an implant over the defect (Figure 1a & 1b; paragraphs 0019-0020); the implant materials include various matrix molecules (paragraph 0026) and combination materials that contain growth factor (paragraph 0039); the implants may be membranes, fixation plates, or three dimensional spatial pieces and fixing means (paragraph 0025) (it is noted that the implants taught by Pirhonen would be considered "units applied to the jaw bone" of the instant claims). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the arrangement of Wikesjö, such as the implants of Figure 1b, for implantation

into defects of the type illustrated by Pirhonen in Fig. 1a, where the defects are severe enough that the tooth had been lost. The placement of an onlay containing a differentiation factor, such as rhBMP-2, in the positioning depicted by Pirhonen in Figure 1 b would have bioactive material in the onlay position, but not at other non-exposed surfaces; this would result in a higher concentration of the bioactive or osteoinductive material presented to the portion of the implant exposed to the open space, covered by the onlay. Wikesjö implies that if 50% (or 5 mm) of the implant is inserted into the bone, that bone can be stimulated to grow over the exposed part (Figure 1). The exposure of the upper outer surface would have been in the range of 20-180°, and 30-120°, depending on where on the upper opening the measurement is made (see Pirhonen, Fig 1a). It would also have been obvious to cover the area with a unit, such as a membrane or a fixation plate, as illustrated by Pirhonen in Fig. 1 b (with an internally curved surface directed toward the outer thread of the implant, which extends over the implant' surface). The motivation to apply the techniques of Wikesjö in this specific type of jaw bone defect would be to implant a tooth into this type of defect, without the requirement of extensive and multiple procedure bone grafts.

It would also have been obvious to apply GSS material to the regions of the implant that are exposed, in order to direct the stimulation of bone growth in these areas, giving the greater degree of exposure being presented with a higher concentration of bioactive or osteoinductive material that the other portions of the implant, required by claim 23. It would also have been obvious to coat the unit with GSS on the surface facing the implant. The motivation would have been to utilize more

of the material in the local region where greater bone stimulation is required. There would have been an expectation of success in view of the formation of bone upon application of rhBMP-2 taught by Wikesjö in both augmentation of alveolar bone and dental implant osseointegration (throughout).

Applicant argues the rejection is improper because the reference does not describe every element set forth in the claims; specifically, the terms "in or on the implant" and the formation of "spaces together with the soft tissue and/or a unit and the upper or lateral surface(s) of the jaw bone" are alleged not to be taught. This argument is not persuasive. As referenced in Figure 1b, Wikesjö teaches experimental treatments (contain the elected differentiation factors, rhBMP-2) are placed/molded around the teeth; the mucoperiosteal flaps are then advanced and sutured to cover the teeth on implants for optimized healing conditions. The carriers (containing the differentiation factors), so used provide and maintain spaces (as described, for example, on p. S1-139, last two paragraphs). The placement and or molding of experimental treatments around the teeth results in a bioactive material "on the implant"; the spaces between implant and soft tissue would be formed and filled by the bioactive material, in the covering of the implants of Figure 1b by the flaps, as taught in the reference.

Applicant argues with respect to claim 22 the references do not account for an implant being offset so that side surfaces or outer thread surfaces of the implant are exposed. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an implant being offset so that side surfaces or outer thread surfaces of the implant

are exposed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim requires exposure to one or more spaces than the other side surface parts or other side outer thread parts. Figure 1 b of Wikesjö meet this requirement, exposure of the exposed thread surfaces to spaces that would be formed when covered, where other surface parts (i.e., those below the jaw line) would not have such exposure. Additionally, Pirhonen in Figure 1 b also depicts exposure that would meet this requirement.

Applicant further argues the combination of references does not account for an exposed surface presenting a higher concentration of bioactive or osteoinductive material than non-exposed surfaces. This limitation is obviated as described above; the placement of an onlay containing a differentiation factor, such as rhBMP-2, in the positioning depicted by Pirhonen in Figure 1 b would have bioactive material in the onlay position, but not at other non-exposed surfaces.

Applicant argues the references do not account for an exposed surface of 20-180° in the circumferential direction and the height direction of the implant. This is not persuasive; the exposure is taught by Pirrhonen in Figure 1 a-b, which meets this limitation.

Applicant argues that the references do not account for a bioactive or osteoinductive coating on the surface of the unit exposed toward the implant. This

would be accounted for by Figure 1b of Wikesjö. The molded rhBMP-2 would be also on the surface of this material, and exposed toward the implant.

Applicant's argument with respect to claim 30 is not relevant since this claim is not under examination.

Applicant argues that Wikesjö teaches away for proceeding as applicants have done by suggesting that first rhBMP-2 should be applied to the jawbone to induce bone growth then anchoring the implant into the new bone growth instead of using rhBMP-2 as part of the implant to induce bone growth. This is not persuasive; Wikesjö is a review article that describes different research approaches to implantation resulting in bone strength to hold an implant. It is not clear how this would somehow be a "teaching away" from applicants approach.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614